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Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (RIN 0938-AU43)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (RIN 0938-AU43), as many of the proposed policies have a significant impact on our members and the patients they serve.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to the various issues raised in the proposed rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposals. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the CY 2022 OPPS and ASC rule.

Proposed Wage Index Policy

For CY 2022, CMS proposes to continue its policy of using the wage index policies and adjustments proposed in the FY 2022 IPPS rule for non-IPPS facilities paid under the OPPS. In the FY 2022 IPPS Final Rule, CMS implemented changes to the wage index policy, including an "imputed floor" policy and extension of the 5% transitional cap. While Vizient appreciates these efforts, we believe more needs to be done to address fundamental issues associated with the wage index. As such, we encourage CMS to explore more comprehensive reform to ensure that the data for the wage index is accurate and that hospitals at the low end of the wage index are paid appropriately.

Proposed Site-neutral Payment Policies for Off-campus Provider-based Departments

Although CMS does not plan to make changes to their previous site-neutral payment policies for CY 2022, Vizient continues to oppose CMS's use of a PFS-equivalent rate for hospital outpatient clinic visits when furnished by excepted off-campus provider-based departments (PBDs). Vizient believes that CMS has undermined congressional intent and is acting outside of their legal authority to implement these payment changes. Vizient reiterates our previous recommendation that CMS restore to hospitals the amounts withheld from them under the 2019 final rule. These cuts threaten patient access to care, especially for vulnerable patients who manage multiple chronic illnesses and who experience adverse social determinants of health.

CY 2022 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS final rule, CMS finalized its proposal to pay for drugs purchased through the 340B Drug Pricing Program at the average sales price (ASP) minus 22.5%, rather than the prior rate of ASP plus 6%. Since 2018, litigation on this issue has continued and on July 2, 2021, the Supreme Court indicated it would hear the parties argue whether the petitioners' suit challenging this payment adjustment is precluded under law.

In the Proposed Rule, CMS acknowledges these legal developments and indicates its continued belief that the Secretary has discretion to propose a payment rate for 340B drugs based on survey results. Yet, the agency does not sufficiently acknowledge ongoing stakeholder concerns regarding the validity of the survey results and ill-conceived administration of the survey, including that data was collected during the start of the public health emergency (PHE). Instead, for CY 2022, CMS proposes to continue the payment rate of ASP minus 22.5%. Vizient continues to have significant concerns with the agency's survey, including that it was administered during the pandemic and after the initial reduction of ASP minus 22.5% was implemented. Further, we are concerned with CMS's overall effort to reduce reimbursement for 340B purchased drugs.

While Vizient supports efforts to address rising drug costs, persistent reductions of crucial Medicare payments to safety-net hospitals and health systems does not

achieve that goal. Instead, it has a detrimental effect of impeding hospitals' ability to utilize 340B savings to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries. We continue to encourage CMS to support providers and our health care system by providing adequate reimbursement of drugs and biologicals purchased under the 340B Program. It is critical, especially due to the COVID-19 pandemic, that our nation's safety-net hospitals and health systems can continue to operate in the areas of our country that need them most. Thus, Vizient continues to encourage CMS to revert to its prior payment policy of ASP plus 6% for 340B-acquired drugs.

These payment cuts, along with other actions of drug manufacturers related to contract pharmacies, are harming hospitals and the patients they serve. In addition, the COVID-19 PHE has shifted the patient mix of several hospitals, and as a result, negatively impacted eligibility for the 340B program. The 340B Drug Pricing Program has been essential to the provision of life-saving prescription drugs; as such, Vizient requests CMS ensure hospitals and other providers can maintain eligibility for the 340B program.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to OPPS
For the past several years, CMS has reviewed non-opioid alternatives and evaluated the impact of packaging policies on access to these products. Based on this review, CMS previously decided to provide separate payments for two drugs (Exparel and Omidaria) when furnished in an ASC. For CY 2022, CMS proposes to continue separate payments for both drugs when furnished in an ASC. The agency is also considering expanding the settings to which this policy applies (i.e., providing separate payment for certain non-opioid pain management drugs), but seeks stakeholder comments. Vizient appreciates CMS's efforts to address the opioid epidemic and provide policies to support the use of non-opioid pain management options, including by separately paying for non-opioid alternatives in settings other than an ASC. Should CMS expand this payment policy to settings beyond ASCs, Vizient encourages the agency to share information regarding how these medications can help reduce opioid prescribing or meaningfully improve pain management. Should similar non-opioid treatments be available that reduce the need for opioids, Vizient suggests the agency consider similar coverage policies.

Proposal to Provide Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals with Transitional Pass-Through Payment Status Expiring between December 31, 2021 and September 30, 2022

In the CY 2021 OPPS/ASC proposed rule, CMS requested comment on whether it should provide separate payment for some period of time after pass-through status ends for devices with expiring pass-through status in order to account for the period of time that utilization for the devices was reduced due to the PHE. In the Proposed Rule, CMS notes that based on stakeholder feedback, the PHE's impact on utilization

and CMS's belief that CY 2020 claims data may not be the best available data for ratesetting purposes, the agency proposes a one-time equitable adjustment to continue separate payment for the remainder of CY 2022 for devices, drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. Vizient understands CMS's equitable adjustment authority is based on Section 1833(t)(2)(E) of the Social Security Act, which states the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Vizient appreciates CMS's efforts to adjust payment policies in light of these concerns. To the extent possible, we encourage CMS to consider whether there is an opportunity to make adjustments in a manner that is not budget neutral to minimize the impact of this policy on other aspects of the OPPS.

Services that will be Paid Only as Inpatient Services

The inpatient only (IPO) list identifies services for which Medicare will only make payments when the services are furnished in the inpatient hospital setting because of the nature of the procedure, the underlying physical condition of the patient or the need for at least 24 hours of postoperative recovery time or monitoring before discharge. Prior to CY 2021, CMS traditionally used five criteria to determine whether a procedure should be removed from the IPO list. In the CY 2021 OPPS Final Rule, the agency finalized a policy to eliminate the IPO list over three years. Beginning in CY 2021, CMS removed 298 codes from the IPO list; these procedures were not assessed against the agency's criteria for removal as the agency had eased its criteria for removal. In the Proposed Rule, CMS proposes to halt the elimination of the IPO list for various reasons, including stakeholder safety and quality concerns related to the procedures removed from the IPO list. Also, the agency indicates the timeframe for finalization would not be sufficient to assess whether a procedure should be payable in the hospital outpatient department (HOPD) setting. Vizient applauds CMS for reversing its position regarding the elimination of the IPO list, as it will help ensure patient safety is consistently considered in the context of broad policy decisions.

In the Proposed Rule, CMS seeks feedback on whether there are services that were removed from the IPO list in CY 2021 that do meet the longstanding criteria for removing services from the IPO list and should continue to be payable in the outpatient setting in CY 2022. Vizient appreciates the agency's interest in stakeholder feedback, as we are aware of certain procedures, such as shoulder replacements, that were performed in an outpatient setting because they were eliminated from the IPO list in CY 2021. As CMS considers which services should be payable in an outpatient setting for future years, Vizient encourages CMS to consider what can be learned as a result of the 2021 IPO list changes, especially as different types of procedures were performed on an outpatient basis. As CMS continues its ongoing review of procedures on the IPO list, we encourage the agency to gain feedback from providers should those procedures be considered for removal from the IPO list in CY 2022 or future years.

Also, the agency proposes adopting its previously used criteria to determine whether a procedure should be removed from the IPO list. Vizient supports the agency's

decision to revert to its prior criteria. We recommend CMS work closely with providers in applying such criteria and to be flexible in their future approaches to the IPO list by carefully considering provider feedback, especially since the criteria would now be provided for in regulation. For example, there may be additional factors beyond the agency's enumerated criteria that should be considered, so it is important the criteria are drafted or interpreted in a way to permit such flexibility.

In addition, Vizient encourages CMS to clarify how different data, such as commercial data, would be considered when applying the criteria, as the patient population may vary significantly from the Medicare population. Consistent with this effort towards clarity, we suggest the agency also provide practical information regarding how providers and others who are interested in collecting or submitting data to CMS may do so as the agency considers removing procedures in the future.

Finally, Vizient discourages the agency from pursuing the longer-term objective of eliminating the IPO list. As anticipated, during CY 2021, Vizient members indicated the policy of progressively eliminating the IPO list created confusion regarding where certain procedures and services should be performed or provided. Given the changes CMS now proposes, we encourage the agency to share additional education regarding the IPO list to ensure it is utilized as intended.

Updates to the Ambulatory Surgical Center Payment System

CMS evaluates the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list; changes to the list are often made in response to stakeholder feedback. From CY 2008 to CY 2020, CMS applied specific exclusion criteria to evaluate whether a procedure could be added to the ASC CPL. In the CY 2021 OPPS/ASC Final Rule, CMS eased the criteria to add procedures to the ASC CPL and added 267 surgical procedures to the ASC CPL. In the Proposed Rule, CMS aims to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulatory text that were in place in CY 2020. Vizient applauds CMS for this proposal, as it better prioritizes patient safety by carefully considering the settings in which various procedures may be provided.

In addition, for CY 2022, CMS proposes to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. Specifically, CMS proposes that external parties (e.g., medical specialty societies, members of the public) could nominate procedures to be added to the ASC CPL. To facilitate this process, for each calendar year, CMS would request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle to be considered in that rulemaking. Vizient believes that CMS's proposal to shift to a nomination process is a positive development that encourages collaboration with external parties and providers. We encourage the agency to provide additional information regarding data needs related to the nomination process, including how data from other payers would be considered and which data collected during 2021 would be helpful to the agency as it decides which procedures to add to the ASC CPL.

OPPS Payment for Specimen Collection for COVID-19 Tests

During the PHE, CMS created HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), and specimen source) in response to the significant increase in specimen collection and testing for COVID-19 in HOPDs. In the Proposed Rule, CMS notes that it presumes this code will be deleted when the PHE ends, but seeks comment on whether it should keep HCPCS codes C9803 active beyond the PHE, including whether it should extend or make permanent the OPPS payment associated with COVID-19 specimen collection.

Vizient appreciates that CMS is considering extending this policy after the PHE, especially considering that testing will likely remain a critical element to detecting COVID-19. Vizient believes it is important CMS ensures adequate reimbursement for specimen collection for COVID-19 tests well after the PHE ends and believes it may be appropriate to permanently adopt this code. Should CMS decide not to retain this code, Vizient believes it is important that the agency provide significant notice and resources to hospitals and other providers to prevent disruption, particularly as certain types of care or certain policies that could extend beyond the PHE may require a COVID-19 test.

In addition, Vizient encourages CMS to take measures to support specimen collection. As such, it is imperative CMS also update payment policies regularly to ensure hospitals receive sufficient compensation for such services beyond the PHE.

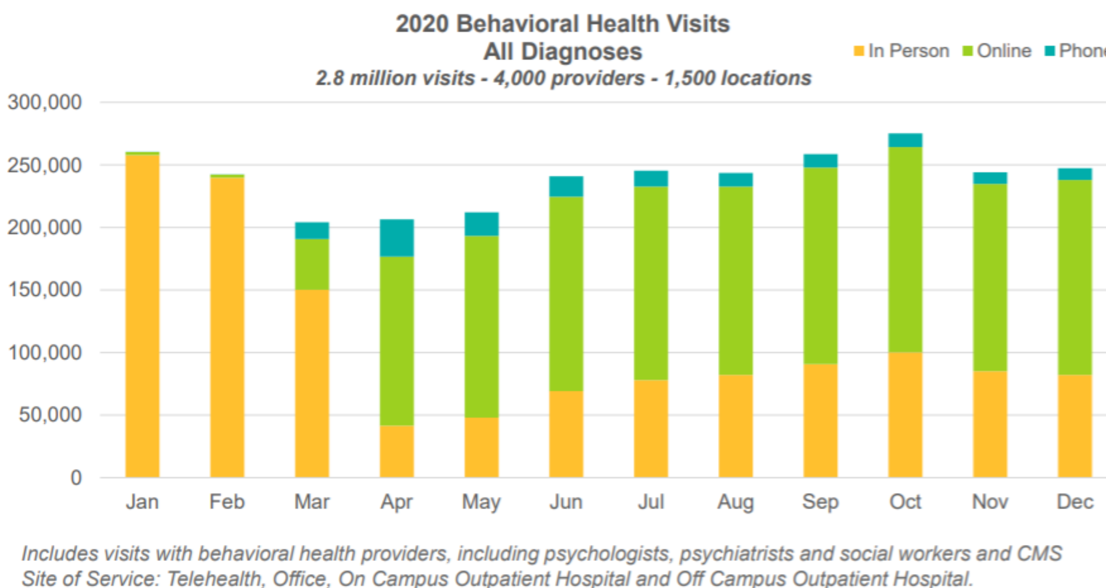
Comment Solicitation on Temporary Policies to Address the COVID-19 PHE

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries at Home

In the Proposed Rule, CMS acknowledges that the Consolidated Appropriations Act (CAA) included a section that expanded the circumstances in which Medicare makes payments for telehealth services under the Physician Fee Schedule (PFS) after the PHE. In Vizient's response to the PFS proposed rule, we appreciated CMS's implementation of this important law, as it will be critical in helping permanently expand access to mental health services furnished remotely. However, we provided various recommendations for the agency to consider, including providing additional flexibility regarding the agency's interpretation of the in-person requirement.

In the Proposed Rule, CMS clarifies that if a beneficiary is receiving mental health services from a hospital clinical staff member who cannot bill Medicare independently for their professional service, then the beneficiary would need to physically travel to the hospital to continue receiving the services post-PHE. Like CMS, Vizient is concerned this could have a negative impact on access. The below table, which relies

on data from the Clinical Practice Solution Center,[1] highlights the different means by which patients received behavioral health visits during the PHE. As shown in the table, a significant portion of visits continue to be provided using online platforms or through the phone. In addition, Vizient notes that we anticipate demand to continue to grow after the PHE.[2] Based on this information, we believe it is critical that the agency provide permanent access to the services, particularly services provided over the phone and through online platforms. Similar to Vizient's comments regarding the PFS proposals, we encourage the agency to minimize barriers to care, such as unnecessary in-person requirements. Also, we are supportive of policies that ensure patients can receive care from a range of providers working in different settings.



Includes visits with behavioral health providers, including psychologists, psychiatrists and social workers and CMS Site of Service: Telehealth, Office, On Campus Outpatient Hospital and Off Campus Outpatient Hospital.

Direct Supervision by Interactive Communications Technology

During the PHE, CMS has allowed direct supervision for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services to be provided through virtual presence. Vizient encourages CMS to continue to allow these services to be provided by virtual presence beyond the PHE and suggests the agency continue to gain stakeholder feedback. Should the agency have specific safety and/or quality of care concerns, we encourage the agency share that information with stakeholders to better understand such issues and to support informed decision making.

Proposed Updates to Requirements for Hospitals to Make Public a List of their Standard Charges

In the CY 2020 Hospital Price Transparency rule, CMS required the public release of hospital standard charge information as a first step in ensuring transparency in health

[1] The Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, is the result of a partnership that works with member practice plans to collect data on provider practice patterns and performance.
[2] *See* Sg2 2021 Impact of Change Forecast Highlights
https://newsroom.vizientinc.com/content/1221/files/Documents/2021_PR_ImpactOfChange.pdf

care prices for consumers. The Hospital Price Transparency rule required hospitals to make certain information publicly available on January 1, 2021. In the Proposed Rule, CMS proposes to change several hospital price transparency policies to ensure compliance with the Hospital Price Transparency rule's disclosure requirements and seeks stakeholder input on a variety of issues. While Vizient appreciates CMS's efforts to improve compliance, we are concerned the agency's steps will impose unnecessary harm and burden on hospitals who are working to help overcome the pandemic and identify new practices and care delivery options.

Increasing the Civil Monetary Penalty Amounts Using a Scaling Factor
In the Proposed Rule, CMS proposes an increase to the Civil Monetary Penalty (CMP) amounts based on a hospital's bed count. Under CMS's proposal, the potential penalty would increase from $300/day to up to $5,500/day for hospitals with more than 550 beds. Vizient is concerned the agency is taking too harsh an approach to encourage compliance, especially in light of the COVID-19 PHE and the significant uncertainty surrounding the agency's approach to compliance. Despite numerous requests to delay the implementation date of the Hospital Price Transparency rule, the rule went into effect in the midst of a global pandemic. Further, given hospitals' limited resources, many are having difficulty determining how best to spend those resources since the rule is so vast and compliance could potentially be achieved in many different ways. Part of hospitals' difficulty has stemmed from a lack of clarity regarding the agency's approach to enforcement and interpretation of the requirements given the newness of the regulation. In addition, Vizient underscores the significant strain on hospital resources due to the pandemic and the substantial cost and administrative burden associated with implementing this rule. As such, Vizient urges CMS to forgo their proposal to increase penalties. Instead, Vizient encourages CMS to provide support to hospitals in need of compliance assistance, as this will more effectively help hospitals comply during this difficult time.

Lastly, Vizient notes that given the newness of the effective date of the rule, which also, as mentioned, coincides with a global pandemic, we believe it is too soon for the agency to take such a heavy-handed approach to compliance. For example, stakeholders trying to understand more effective implementation plans or identify how best to communicate information to the public may have wanted to wait to see which approaches were most beneficial before selecting a plan. Vizient encourages CMS to refrain from increasing penalties at this time until hospitals are given a better opportunity to comply and learn from others.

Prohibiting Additional Barriers to Accessing Machine-readable File
In the Hospital Price Transparency rule, CMS provided that a hospital would have discretion to choose the Internet location it uses to post its file containing the list of standard charges, so long as the comprehensive machine-readable file is displayed on a publicly-available webpage, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data is easily accessible, without barriers, and can be digitally searched. In the Proposed Rule, CMS provides various concerns related to access. The agency proposes to clearly specify that although the hospital has flexibility in how it ensures the standard charge information is "easily accessible", it clarifies the steps a

hospital should take in determining whether the information is easily accessible based on access barriers the agency has learned of during compliance reviews (e.g., ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website). Instead of imposing additional regulatory requirements, Vizient instead encourages the agency to identify practices that support access to the machine-readable file so that hospitals are given the knowledge and time to tailor different strategies to their organization.

Clarification of the Price Estimator Tool Option and Considerations for Future Price Estimator Tool Policies

As CMS is aware, the No Surprises Act passed in December 2020 and elements of that law overlap with or can build upon elements of the Hospital Price Transparency rule. In the Proposed Rule, CMS clarifies the expected output of hospital online price estimator tools, which may be used instead of a hospital posting its standard charges for the required shoppable services in a consumer-friendly format. Specifically, in the Proposed Rule, CMS emphasizes its view that "tailored to individuals' circumstances" includes the need to provide real-time individualized out of pocket estimates. As provided by CMS, such estimates are to combine hospital standard charge information with the individual's benefit information directly from the insurer, or the self-pay amount. On August 20, 2021, the Department of Health and Human Services and others, released an FAQ[3] which addresses other regulatory and statutory requirements related to price comparison tools, including overlapping requirements. Vizient encourages CMS to consider additional regulatory activities that may influence compliance plans and for the agency to help educate providers and provide technical assistance to providers challenged with this element of the hospital price transparency rule and other related regulatory requirements. Further, Vizient encourages CMS to coordinate with other departments to minimize burden on providers and ensure patients are not confused by all the information made available.

Improving Standardization of the Machine-Readable File

Vizient appreciates the value of standardization in many aspects of health care, such as for electronic health records. In the Proposed Rule, the agency seeks feedback on various issues related to standardization (e.g., best practice for formatting data, additional data elements to be made mandatory, etc.). The agency notes it seeks more standardization to meet the goal of permitting comparisons of standard charges among providers.

Vizient is concerned that a mandate to standardize such data would be excessively burdensome and redundant, particularly since the requirements have already been implemented differently by many hospitals. We also note that regarding comparisons, issues still persist with other systems that work to inform patients about hospital quality and whether these systems truly achieve their goal. Similarly, a price comparison tool that aims to incorporate other factors would be similarly difficult to

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[3] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs%20About%20ACA%20%26%20CAA%20Implementation%20Part%2049_MM%20508_08-20-21.pdf

implement and could confuse patients. Before CMS further considers this policy, Vizient urges the agency gain targeted feedback from providers and other stakeholders to better understand potential concerns and guardrails that would need to be in place should such a policy advance.

Radiation Oncology Model

The Radiation Oncology (RO) Model is a mandatory model that is designed to test whether prospective episode-based payments for radiotherapy (RT) services will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. In addition, the RO Model is to include 30% of all eligible Medicare fee-for-service RO episodes nationally.

Although CMS engaged in prior rulemaking on the RO Model, due to the COVID-19 PHE, the agency delayed the start of the RO model. In addition, the CAA, which passed in December 2021, prohibited implementation of the RO Model until January 1, 2022, at the earliest. In the Proposed Rule, CMS proposes to begin the RO Model on January 1, 2022 and end the model on December 31, 2026, maintaining a five-year duration. Vizient continues to voice our previous concerns about mandatory models and discourages the agency from continuing to impose them. In addition, Vizient notes that it may be challenging for some hospitals to prepare for the January 1, 2022, deadline, particularly given the impact of COVID-19. We encourage the agency to be mindful of this strain and to monitor its impacts on model participants.

Also, given the impact of the pandemic on different geographic areas, Vizient is concerned that participant's results may be skewed, among other issues. Vizient appreciates that CMS proposes an extreme and uncontrollable circumstances (EUC) policy but believes that the EUC's effectiveness in reducing administrative burden will also depend on stakeholder awareness and notice and communication of changes. Therefore, to the extent CMS utilizes an EUC, we encourage the agency to provide significant notice and to also work closely with stakeholders to better ensure the adjustments meet their needs. In addition, Vizient notes that other changes, such as updates to the baseline period, case mix and trend factor may be warranted to prevent certain providers from being disadvantaged due to the COVID-19 PHE. We encourage the agency to listen to recommendations from providers regarding the most appropriate adjustments.

In the Proposed Rule, CMS indicates its aim to exclude brachytherapy from the RO model. Should CMS finalize this exclusion, the agency should ensure these services are covered. Also, Vizient notes that some members have raised concerns with the inclusion of proton beam therapy in the model. As a result, Vizient suggests CMS consider the appropriateness of proton beam therapy in the RO model as payment under the model may be inadequate when such costly therapies are provided.

More broadly, Vizient recommends CMS carefully monitor the RO Model design, especially since it is mandatory and therefore will broadly impact providers and patients. For example, Vizient is concerned CMS is proposing to reduce the discount factors for the Professional Component (PC) and Technical Component (TC) by 0.25% each. Vizient is concerned these cuts, along with other cuts to the PFS payment rates, will make it more difficult for providers to sustainably participate in the model and provide care.

Requirements for the Hospital Outpatient Quality Reporting Program

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the Hospital Inpatient Quality Reporting Program (IQR Program). Hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the outpatient department (OPD) fee schedule increase factor. In the Proposed Rule, CMS indicates it is seeking to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the hospital outpatient setting. Although CMS is proposing to halt the elimination of the IPO list, it anticipates that as technology and surgical techniques advance, services will continue to transition off the IPO list and become payable in the outpatient setting. To support measure alignment between programs, Vizient encourages CMS to potentially adopt future measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting. As CMS considers developing such measures, we recommend the agency ensure it does not impose administrative burdens on providers.

Request for Comment on Potential Future Efforts to Address Health Equity in the Hospital OQR Program

Vizient appreciates CMS efforts to expand efforts to address health equity and has previously provided recommendations for the agency's consideration in our comments to CMS on the IPPS Proposed Rule. In our comments, we note various concerns with indirect estimation methods and encourage CMS to improve and support providers' efforts to collect demographic data.

Request for Information on Rural Emergency Hospitals

The Proposed Rule includes an RFI on a variety of questions about how the agency should approach the establishment of Rural Emergency Hospitals (REHs). As noted above, Vizient serves a diverse membership of hospitals in rural America, including independent community hospitals, sole community hospitals, critical access hospitals, rural health clinics and other non-acute providers. Vizient strongly believes that it is essential to support a vibrant and high-quality health care system that ensures access to care for patients in rural and underserved areas.

We are encouraged that the establishment of the new REH designation may provide a critical lifeline that would maintain the ability for struggling rural hospitals to continue serving patients. While there are several statutory limitations that may limit the attractiveness of the program (e.g., the elimination of inpatient beds), Vizient is

encouraged by the scope and the level of detail in the questions raised by the agency in the RFI. We commend CMS for its recognition of the complex challenges and considerations posed by the model and are hopeful the agency will continue expansive stakeholder engagement to support a robust and accessible model. Vizient is pleased to offer our feedback and recommendations on the REH RFI. While we will not address every question directly, we thank you for the opportunity to share our views to help support the establishment of a successful REH program.

Obstacles to REH Success
In the RFI, CMS seeks feedback on the obstacles to establishing an REH. The examples raised in the question (staffing shortages, transportation and sufficient resources) are the clear and most challenging obstacles to establishing and operating a successful REH. Even for financially stable acute care hospitals, recruiting and retaining clinical staff, including physicians, advanced practice clinicians, nurses and other clinical and peri-clinical staff (e.g., phlebotomist, lab technicians) is an enormous challenge that has only been exacerbated by the COVID-19 pandemic. Hospitals are now facing critical staffing shortages and growing staffing costs across the country, with rural areas seeing many of those problems amplified. While Vizient is supportive and hopeful for the success of the REH model, further incentives may be needed to support a robust health care workforce throughout the country, but especially in rural America.

Vizient also believes that a lack of clarity regarding converting facilities' ability to maintain eligibility for the 340B Drug Pricing Program will serve as a deterrent for some facilities in making REH determinations. It is essential that the regulations establishing the new REH designation clarify that current 340B covered entities maintain their eligibility in the program.

Another key obstacle for converting facilities would be the risk of overly burdensome administrative challenges, such as cumbersome conditions of participation (CoPs) or labor-intensive reporting requirements. Such an approach would discourage facilities from converting to the new safety-net model and prevent converting REH's from being successful.

Types and Scopes of Services to be Offered
The agency seeks feedback on specific outpatient services that should be offered through REHs. Vizient believes that REHs should be granted significant flexibility in determining what services are needed and can be supported in their markets. If an REH determines it can offer a wide array of services, there are few outpatient services that should not be allowed where it is clinically safe to do so. Alternatively, if the population and resources do not support a variety of services, few should be required if doing so would be operationally and financially unrealistic.

Among the dedicated services that should be offered, Vizient believes there is evidence to support the ability of REHs to serve as a hub for primary care services, including offering services like care coordination, cancer screening and chronic care management. REHs could also serve as an access point for specialists' consultations, offer virtual triage to help patients find the level of care they need at the lowest cost, in

the most appropriate setting, as well as provide connections for eEmergency and eHospitalist services that could bridge gaps resulting from staffing and volume challenges via telehealth.

As the nation continues working to address challenges with maternal health and infant mortality, maintaining access to maternal care services continues to be a vital need in rural communities. Virtual Maternal and Fetal Medicine is an appropriate virtual service and should be encouraged or incentivized as an important service to offer at all REHs. In addition to a wide array of primary care and maternal health services, REHs could offer meaningful mental and behavioral health support. Vizient would urge CMS to consider substantial flexibility in how REHs could provide those services, including via onsite telehealth supports, providing medication assisted treatments and offering discreet, off-site affiliated locations to provide stigma-free care settings.

While the agency is taking steps to promote widespread availability of behavioral health care through telehealth after Congress permanently expanded access through the CAA, there remains in place the requirement that patients are seen in-person once every six months as a requirement for coverage once the COVID-19 PHE ends. As described in Vizient's Physician Fee Schedule comments, we encourage the agency to consider alternatives that would allow a broader array of practitioners to fulfill that in-person obligation, as long as the in-person visit requirements remain in place.

Standards, Conditions of Participation and Licensing
Vizient is hopeful that the new REH option may offer a meaningful lifeline for struggling rural hospitals. As the agency moves forward with implementing regulations, we strongly encourage the agency to allow the conversion to, and operation of, an REH to be as free from complex regulatory licensure and other administrative burdens as possible. To the extent feasible, we encourage CoPs, quality measures and licensure to largely mirror those currently utilized by the converting facility, with recognition of resource limitations at converting facilities. Many of the facilities that are most likely to consider adopting the new model are already facing difficult financial situations and will be limited in their ability to adapt to new requirements or resource intensive reporting obligations. By carrying through existing reporting and CoP regimes where possible, many converting facilities will be better able to adapt to familiar reporting structures. At the same time, we encourage the agency to consider to what degree those existing requirements can be safely scaled back to avoid unnecessary administrative burden.

Similarly, with the growing maturity of virtual supervision for care delivery, REHs should be allowed and encouraged to utilize lower cost staffing options that maximize the role of advanced practitioners and virtual services.

Health Equity
Vizient shares the commitment of the agency in taking steps to make meaningful improvements to health equity. As the agency knows, avoiding rural hospital closures and the loss of many key services would be an effective approach in supporting health equity. Ensuring communities increase access, or at least do not lose an important

access point, to a wide array of health care services should be a priority when establishing an REH.

With that in mind, by granting flexibility while encouraging REHs to offer a robust array of primary care services, maternal and fetal health care and access points to opioid and substance use disorder treatments, significant improvements can be made to address a several factors that contribute to adverse health care outcomes in rural areas.

Recognizing the importance of identifying and correcting deficiencies in care delivery that lead to health disparities, Vizient encourages the agency to prioritize efforts to improve data collection and accuracy and leverage those efforts to assist hospitals in highlighting disparities and collaboratively working to identify what steps can be taken to improve outcomes.

Vizient has provided more detailed comments to the RFI on improving health equity in response to the Inpatient Prospective Payment System proposed rule.

Enrollment Process
Given the circumstances that may drive smaller hospital facilities to convert to an REH, Vizient believes that converting to an REH should be direct and simple to accomplish. Additionally, entities that do convert should be afforded the opportunity to rotate out of the program and resume operations under their previous hospital designation (CAH, SCH, etc.). Hospitals able to regain financial footing under the REH model should be allowed to easily resume offering inpatient services when practical if they are financially able to do so. Similarly, given the wave of rural hospital closures in recent years, consideration should be given to the potential to allow recently closed facilities to re-open as an REH.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs – Request for Information

As part of CMS's efforts to modernize its quality measurement enterprise, the agency included an RFI in the Proposed Rule to inform the agency as it transitions to digital quality measurement. Vizient encourages CMS to review our responses to this RFI, as provided in our comments to the inpatient prospective payment system (IPPS) proposed rule. We also note our interest in collaborating with CMS to provide our expertise and insights to inform future agency efforts. Finally, we encourage CMS to carefully implement policies related to this RFI, as the data's reliability should be prioritized over a fast implementation timeline.

Closing the Health Equity Gap in CMS Clinician Quality Programs – Request for Information

Vizient commends CMS in its efforts to provide more transparency regarding health inequities and disparities, either in resources provided or outcomes by healthcare organizations. Vizient encourages the agency to review our recommendations

regarding future potential stratification of quality measure results by race and ethnicity and improving demographic data collection, as provided in our comments in response to the IPPS proposed rule.

Conclusion

Vizient welcomes CMS's efforts to update policies under the outpatient prospective payment system and its emphasis on stakeholder feedback. We believe this provides a significant opportunity to help inform the agency on the impact of specific proposals based on learned insights.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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